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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,723	06/23/2003	David L. Canfield	A279-USA	8759

24677 7590 09/06/2006

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EXAMINER	
KRAMER, NICOLE R	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,723	CANFIELD ET AL.	
	Examiner	Art Unit	
	Nicole R. Kramer	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-5 and 10-24 are rejected under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 4,071,032 (hereinafter referred to as Schulman '032) in view of U.S. Patent No. 5,405,367 (hereinafter referred to as Schulman '367).

With respect to claims 1-4, Schulman '032 discloses an elongated hollow tube formed of ferrite, said hollow tube defining an interior region thereof for housing corresponding microstimulator electronics (Schulman discloses a metal, ferrite can 55 which houses the internal components of a pacemaker except for an externally wound coil 37; see col. 10, lines 7-62, especially 52-55. See also col. 11, lines 5-21 and col. 12, lines 15-29 which further describe container 55 for encapsulating the pacemaker internal components. See also col. 11, lines 55-57 which describe that can 55 may be made of a different material and a ferrite coating may be applied thereto, which Examiner notes would satisfy the requirements of the tube being "formed of a magnetic field concentrated material."). Schulman further discloses an electrically conductive wire coil wound around an outer surface of the hollow tube and adapted for electrical

communication with the microstimulator electronics (Schulman discloses that coil 37 is wound around the outside of metal can 55; see Figs. 5 & 7 and associated text at col. 7, lines 34-60 and col. 10, lines 63-65; col. 12, lines 15-30. Further, the end 38 of coil 37 is connected to the internal pacemaker circuitry housed within the can; see col. 7, lines 49-60). Lastly, Schulman also discloses that the assembly of the coil 37 wound about the metal can is enclosed within a hermetic container 74 formed of glass and/or ceramic to insulate them from contact with body fluids (see col. 2, lines 60-65; see also Fig. 8 and associated text at col. 12, lines 35-65).

The metal can 55 of Schulman '032 is not cylindrical, but the teachings of Schulman '032 are applicable for use with or forming part of any implantable living tissue stimulator (see col. 3, lines 24-28 of Schulman '032). It is known in the art to construct the housing for microstimulator electronics in a cylindrical, tubular fashion. For example, U.S. Patent 5,405,367 to Schulman teaches a microstimulator having a tubular housing 22 to provide a small size that allows for easy implantation through the lumen of a hypodermic needle (see for example, col. 3, lines 56-60 and see col. 6, lines 25-35. See also U.S. Patent No. 6,214,032 to Loeb and U.S. Patent No. 4,333,469 to Jeffcoat et al. for other examples of cylindrical, tubular microstimulator housings). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the metal can 55 of Schulman '032 such that it is a cylindrical, tubular shape having very small dimensions as taught by Schulman '367 in order to allow for easy implantation of a microstimulator through the lumen of a hypodermic needle.

Regarding Claims 5, Schulman '032 discloses that the pacemaker circuitry may be mounted on an appropriate support structure, e.g., an integrated circuit board (see col. 12, lines 21-24).

Regarding Claim 10, Schulman '032 discloses a rechargeable battery and rectifier circuit, wherein currents generated in the coil are rectified and used to recharge the battery (see col. 2, lines 53-60; see also col. 3, lines 44-53 and col. 7, lines 49-60).

Regarding Claim 11, Schulman '032 discloses RF transmission and receiver circuitry, wherein the coil serves as an antenna (see col. 2, lines 53-60; see also col. 11, lines 26-33).

Regarding Claims 12-14 and 18-21, Schulman '032 does not explicitly disclose that the ferrite tube has an inner diameter of about 1.78mm, outer diameter of about 2.26mm, and axial length of about 3mm, that the ceramic sleeve has an outside diameter in the range of about 3.2 to 8.0mm. As previously described, Schulman '367 discloses an implantable microstimulator that includes IC circuits wrapped by ferrite plates and a coil (Figs. 3 & 4, element 11; Col. 10, lines 22-30). Schulman '367 further discloses that the microstimulator should have a diameter of about 2mm and an axial length of about 10 mm. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the microstimulator of '032 to include tube and sleeve dimensions that allow for overall microstimulator dimensions on the order of 2 mm x 10 mm as taught by Schulman '367 in order to provide a small size that allows for easy implantation through the lumen of a hypodermic needle ('367, Col. 3, lines 56-60).

Regarding Claims 15 and 22, Schulman '032 discloses the use of several coil turns (Col. 7, lines 42-43), which Examiner considers to anticipate the lower end of Applicant's broad range of about 10 Turns. Alternatively, Schulman '367 discloses an implantable microstimulator that includes IC circuits wrapped by ferrite plates and a coil, wherein it is taught to provide approximately 200 turns of the coil in order to provide the necessary inductance (Figs. 3 & 4, element 11; Col. 10, lines 22-30). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the microstimulator coil of Schulman '032 to include approximately 200 turns as taught by Schulman '367 in order to provide the necessary inductance.

Regarding Claims 16 and 23, Schulman '032 fails to specifically disclose that the coil wire is about 44 gauge. Schulman '367 discloses that the microstimulator's coil should be of approximately 51-gauge wire. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the microstimulator coil of '032 to include wire that is approximately 51 gauge as taught by Schulman '367 in order to provide the necessary inductance ('367, Col. 10, lines 24-25) and to minimize any increase in the diametric dimension necessitated by the coil. Examiner considers "about 44 gauge" to encompass approximately 51-gauge wire. Further, Examiner notes that it would have been an obvious matter of design choice to modify coil to be 44 gauge wire, since applicant has not disclosed that such a gauge size solves any stated problem or is for any particular purpose and it appears that the claimed invention would perform equally well with other gauge size wires, including the 51-gauge wire of the '367 Schulman patent.

3. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman '032 in view of Schulman '367, as applied above to claim 5, and further in view of U.S. Patent No. 6,245,092 ("Schaldach, Jr.").

Schulman discloses that the pacemaker circuitry may be mounted on an appropriate support structure, e.g., an integrated circuit board (see col. 12, lines 21-24). Schulman does not explicitly disclose that the integrated circuits are interconnected by a flex circuit and folded in a face-to-face fashion. Schaldach, Jr. disclose integrated circuitry for use in implanted medical devices, wherein the circuitry is interconnected on a folded, flexible substrate (Fig. 3, elements 5-5.4 & 11; Col. 2, lines 17-24 & 54-64; Col. 3, lines 30-46). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teachings by Schaldach, Jr. to modify the integrated microstimulator circuitry of Schulman to include integrated circuits that are interconnected by a flex circuit and folded in a face-to-face fashion. The motivation would have been to provide increased compactness and miniaturization as well as simplification in surgical implantation and improved patient tolerance (Schaldach, Jr., Col. 1,lines 30-37; Col. 2, lines 14-16).

4. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman '032 in view of Schulman '367, as applied above to claim 5, and further in view of U.S. Patent No. 4,333,469 ("Jeffcoat et al.").

Schulman discloses that the pacemaker circuitry may be encapsulated by material 25 (see Fig. 1 and associated text at col. 3, lines 54-68; see also col. 12, lines 39-41), but fails to disclose that the potting matrix is formed out of silicone. Jeffcoat et al. teaches an implantable microstimulator for stimulating bone growth. The circuitry of the microstimulator is housed in a bullet-shape case, and the circuitry is potted in silicone elastomer (see Abstract). The silicone potting matrix is disclosed as ideal for preventing ionic contamination of the circuit, thus making silicone a better choice as the potting material than epoxy because epoxy is not well suited for long life (see Abstract and col. 10, lines 6-27). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the potting material 25 of Schulman '032 such that it is silicone as taught by Jeffcoat et al. in order to effectively prevent ionic contamination of the circuitry.

5. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman '032 in view of Schulman '367 and further in view of U.S. Patent No. 4,333,469 ("Jeffcoat et al."), as applied above to claim 8, and further in view of U.S. Patent No. 6,164,284 ("Schulman '284").

Schulman '032/Jeffcoat et al. fail to explicitly disclose that the potting matrix includes a getter for absorbing any water introduced within the interior of the circuitry housing. Schulman '284 discloses an implantable microstimulator that includes IC circuits wrapped by ferrite plates and a coil and also teaches the use of a getter (Fig. 1; Figs. IA&B; Col. 4, lines 10-36; Col. 13, lines 40-47). It would have been obvious to one

of ordinary skill in the art at the time of Applicant's invention to modify the silicone potting matrix of Schulman '032/Jeffcoat et al. to include a getter as taught by Schulman '284 to increase the hermeticity of the implanted stimulator by absorbing fluid introduced therein (see Schulman '284, Col. 13, lines 43-47).

Response to Arguments

6. Applicant's arguments filed 8/9/2006 with respect to claims 1-24 have been considered but are not persuasive.

7. Applicant first argues that Schulman '032 does not disclose a tube formed of ferrite because the addition of ferrite slabs or a coating onto a metal can 55 does render the metal can as being formed of ferrite (see pages 2-3 of Response filed 8/9/06). Examiner respectfully disagrees. As pointed out by Applicant, the metal can in Schulman '032 may be surrounded by ferrite slabs so as to form a ferrite box (see col. 10, lines 52-56), or may have a ferrite coating or powder permanently attached to the surface thereof (see col. 11, lines 54-66). All of these configurations are considered to form a structure which is formed of ferrite. When the ferrite slab(s) or coating is attached to the metal box, Examiner considers the result to be a single structure or tube. Further, the single structure or tube is considered to be formed of ferrite since the slab(s) or coating is formed of a ferrite material.

8. With respect to claims 10 and 11, Applicant argues that only one single coil is claimed by Applicant and such coil performs the multiple functions of recharging the battery and acting as the antenna (see pages 4-5 of Response filed 8/9/06). However, claims 10 and 11 are separate claims, each having separate subject matter and each depending from claim 1. The features upon which applicant relies (i.e., a single, multi-functional coil) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

9. With respect to claims 15 and 22, Applicant argues that both of the above rejections address only a single valued coil turn number rather than the claimed coil range (see pages 5-6 of Response filed 8/9/06). In order to anticipate the claimed range, the reference need only disclose a single value number that falls within the range. Examiner does not need to cite a reference reciting the entire claimed range. In addition, in response to the argument that "Examiner is trying to have it both ways" by challenging both the lower coil turn number and the higher coil turn number, Examiner notes that Applicant's claimed range of 10-600 turns is incredibly broad. Examiner has simply provided Applicant with multiple teachings that both lower and higher coil turn numbers are known in the art, depending the desired characteristics of the coil.

10. With respect to claims 6 and 7, Applicant argues that Schaldach '092 is related to pacemakers and thus would not to combined with the subsized hollow cylindrical tube

claimed by Applicant (see pages 6-7 of Response filed 8/9/06). However, Schaldach '092 explicitly states that the disclosed highly integrated electronic circuit provides increased compactness and miniaturization as well as simplification in surgical implantation and improved patient tolerance (Schaldach, Jr., Col. 1,lines 30-37; Col. 2, lines 14-16). One of ordinary skill in the art would be motivated to utilize the teachings of Schaldach '092 in any implantable living tissue stimulator, since compactness, miniaturization, simplification in surgical implantation, and improved patient tolerance are considerations for all implantable stimulators.

11. With respect to claim 8, Applicant is basically arguing that Jeffcoat is not analogous art since Jeffcoat is directed to bone growth stimulators (see pages 7-8 of Response filed 8/9/06). Examiner considers all implantable living tissue stimulators to be analogous art, and believes that one of ordinary skill in such art would consider the teachings of Jeffcoat when designing a neuromuscular microstimulator. The teaching that the stimulator circuitry is potted in silicone elastomer because such material is ideal for preventing ionic contamination of the circuit, thus making silicone a better choice as the potting material than epoxy because epoxy is not well suited for long life (see Abstract and col. 10, lines 6-27) would be relevant and applicable to all implantable stimulators. In addition, Applicant argues that the claimed invention is concerned with hermiticity and ionic contamination, and thus would not consult the teachings of the Jeffcoat. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for

patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

12. With respect to claims 12-14, 18-21, and 23, Applicant argues that the metal can 55 Schulman '032 forms a pacemaker and thus one of ordinary skill in the art would not be motivated to modify the metal can to be cylindrical and having the very small dimensions of Schulman '367 for easy implantation through the lumen of a hypodermic needle (see pages 8-12 of Response filed 8/9/06). However, Schulman '032 is not solely directed to cardiac pacemakers - rather, the teachings of Schulman '032 are applicable for use with or forming part of any implantable living tissue stimulator (see col. 3, lines 24-28 of Schulman '032). Thus, Examiner maintains that it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the microstimulator of '032 to include tube and sleeve dimensions that allow for overall microstimulator dimensions on the order of 2 mm x 10 mm as taught by Schulman '367 in order to provide a microstimulator having a small size that allows for easy implantation through the lumen of a hypodermic needle. Schulman '032 is directed towards providing an improved implantable rechargeable living tissue stimulator (see col. 1, lines 52-60 and col. 2, lines 26-29) by providing the pickup coil winding outside the metal housing in order to improve the pickup efficiency of the coil (see col. 7, lines 34-40). Further, ferrite slabs or a coating are provided on the metal housing in order to increase the magnetic field passing through the coil and protecting the stimulator circuitry for heat or interference due to the external magnetic field (see

col. 2, lines 49-55). Such teachings would be relevant and applicable to all implantable stimulators, including the cylindrical microstimulator of Schulman '367.

13. With regard to claim 16, Applicant argues that the claimed invention is not concerned with inductance, and thus using inductance as the basis for the claim rejection has no relevance to the claims as presented (see pages 10-11 of Response filed 8/9/06). The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Further, Examiner maintains that "about 44 gauge" encompasses approximately 51-gauge wire because the term "about" is not explicit in scope. In addition, Examiner notes that it would have been an obvious matter of design choice to modify coil to be 44 gauge wire, since applicant has not disclosed in the specification that such a gauge size solves any stated problem or is for any particular purpose and it appears that the claimed invention would perform equally well with other gauge size wires, including the 51-gauge wire of the '367 Schulman patent.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRK
8/21/06

George Manuel
Primary Examiner